



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: FISHER CLINICAL SERVICES, INC.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers,

distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on August 26, 2015, Fisher Clinical Services, Inc. 7554 Schantz Road, Allentown, Pennsylvania 18106 applied to be registered as an importer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Methylphenidate (1724)	II
Levorphanol (9220)	II
Noroxymorphone (9668)	II
Tapentadol (9780)	II

The company plans to import the listed substances for analytical research, testing, and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol for distribution to its customers. Placement of these (this) drug code (s) onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: December 9, 2015.

Louis J. Milione,
Deputy Assistant Administrator.

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